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(54) System and method for flow triggering of breath supported ventilation.

(55) The system and method for flow triggering breath supported ventilation include a source (12, 14) of a predetermined, preinspiratory, constant flow of breathing gas to a patient, one or more flow sensors (16, 18, 32, 41, 42, 43) for measuring the rate of gas flow in a flow path communicating with the patient, means (46) for determining when inhalation from the flow path has occurred, and means (20, 22) for generating breath support in the delivered gas flow in response to inhalation by the patient, means (44) to terminate breath support when inspiratory phase concludes, and means (46) to re-establish the predetermined, preinspiratory, continuous flow of breathing prior to the patient's next inspiratory effort. A plurality of individual gas sources (12, 14) preferably provide a controlled mixture of breathing gas. In combination with breath support to the patient during the inspiration effort, the flow triggering strategy of the invention offers significant improvements in providing breath support to patients having weakened respiratory capabilities.

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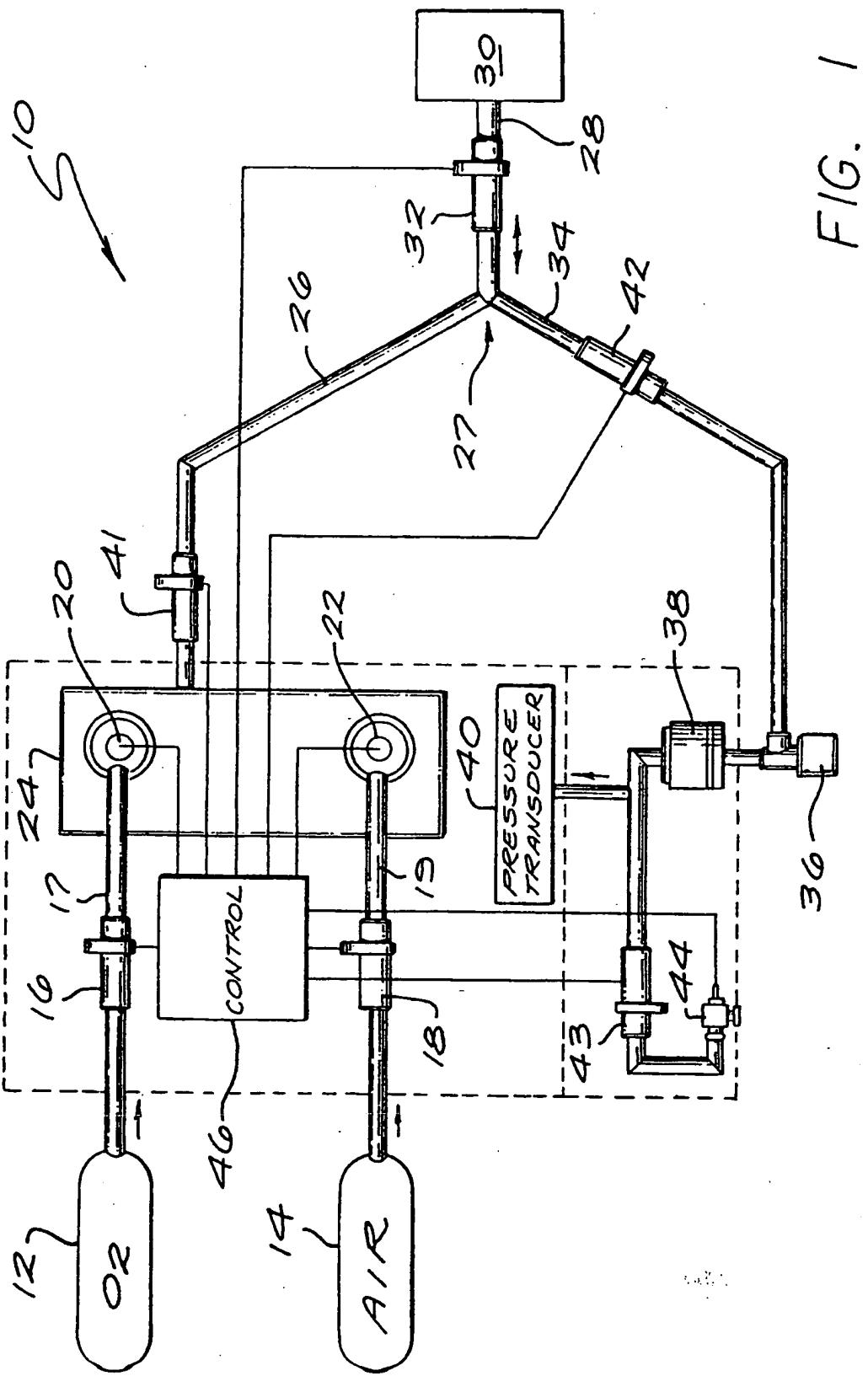


FIG. 1

This invention relates generally to breathing ventilators, and more particularly relates to a pneumatically driven, electronically controlled, ventilator system for providing breathing gas to a patient, and a system and method for flow triggering breath support during patient-initiated spontaneous breathing.

Breathing ventilator systems conventionally provide a breathing gas for either non-pressure supported breaths during inspiration at a pressure level typically no more than 2 cm. of water above or below the pressure baseline or pressure-supported breaths of breathing gas at a support pressure during inspiration as high as 70 - 100 cm. of water. Pressure support is also known in the art by other names, e.g. inspiratory assist, pressure assist, or inspiratory pressure assist. Such breathing gas is often supplemented with a higher proportion of oxygen than is found in the ambient atmosphere. The respiration work performed by a patient on a ventilator may be divided into two major components: the work to initiate a breath and the work to sustain a breath. It is desirable to reduce the effort expended by the patient in each of these phases, since a high level of such effort can cause further damage to a weakened patient or be beyond the capabilities of small or disabled patients. As discussed below, a variety of strategies and systems have been developed to address these problems, but important issues still remain in the reduction of work demanded by ventilators to command and sustain a breath.

Ventilators presently known in the art are commanded to deliver inspiration support, or a specific flow of breathing gas during an inspiratory phase of breathing, based upon a "pressure trigger" as described below. With such a system, when a patient's spontaneous inspiratory effort withdraws a small volume of gas from the breathing-gas circuit, the corresponding drop in pressure in the closed ventilator circuit is monitored, and when a predetermined triggering pressure threshold is reached, a control mechanism causes the ventilator's pneumatic system to deliver breathing gas at the desired pressure or flow rate. This activation of the ventilator cycle by means of a patient-induced negative pressure may be termed "pressure triggering". A certain amount of lag time and associated negative pressure always occurs between the onset of inspiratory effort and the time that the gas pressure or flow reaches the patient's airway. This lag time (or delay) is generally referred to as a ventilator's response time, and commonly occupies a small but significant portion of a patient's total inspiration time.

To circumvent or overcome the problems associated with breath triggering in the context of a closed ventilator circuit, a continuous flow system may be employed. To ensure that the patient receives a flow of breathing gas immediately upon initiation of an inspiratory effort and with the appropriate oxygen concentration, a flow regulator is positioned at the

inlet of the breathing-gas circuit to deliver a constant gas flow in excess of the peak-flow demand expected from the patient. This "continuous flow" approach eliminates the ventilator's delay time and significantly reduces the negative pressure work associated with closed ventilator systems.

An advantage of the continuous gas flow (available in an open breathing-gas system) is that a patient's inspiratory effort results in an immediate flow of breathing gas into his/her trachea, without the delays and with less negative pressure work inherent in closed ventilator systems. Thus, it would be desirable to provide pressure support to a patient in an initially, open continuous-flow system rather than from a closed breathing gas system. It would also be desirable to provide a method and system for triggering breaths which can be made to be more sensitive than previous pressure-based strategies.

The invention provides a method of flow triggering of breath supported ventilation in a functionally open breathing-gas circuit, which method comprises:

delivering a predetermined rate of flow of breathing gas from a source to a patient and generating breath support in the determined flow of gas when the patient inhales characterised in that inhalation is determined by measuring the change in the rate of gas flow in said ventilation flow path due to inhalation;

breath support in said delivered flow of gas is provided when said change in the rate of gas flow due to inhalation exceeds a predetermined threshold value; and

restoring the preinspiratory, continuous flow of breathing gas to a predetermined value before the patient's next inspiratory effort.

The invention further provides a system of flow triggering breath support ventilation for use in a functionally open breathing-gas circuit having means to supply a predetermined, preinspiratory, continuous gas flow from a source of breathing gas to a patient via a flow path characterised by flow sensor means for measuring the rate of gas flow in said flow path due to inhalation;

means responsive to said flow sensor means for generating breath support in said delivered flow of gas when said change in the rate of gas flow due to inhalation exceeds a predetermined value; and

means for restoring the preinspiratory, continuous flow of a breathing gas to its predetermined value before the patient's next inspiratory effort.

A specific example of a ventilator system according to the invention will now be described with reference to the accompanying drawings, in which:-

Figur 1 is a schematic diagram of a flow-triggered, open circuit ventilation system;

Figur 2a shows a graph of pressure measurements v r time for a typical pressure-triggered breath without pressure support;

Figur 2b shows a graph of flow measurements

over time for a typical pressure-triggered breath without pressure support;

Figure 3a shows a graph of pressure measurements over time for a typical pressure-triggered, pressure-supported breath;

Figure 3b shows a graph of flow measurements over time for a typical pressure-triggered, pressure-supported breath;

Figure 4a shows a graph of pressure measurements over time for a typical flow-triggered, pressure-supported breath;

Figure 4b shows a graph of flow measurements over time for a typical flow-triggered, pressure-supported breath;

Figure 5a is an illustration of the patient flow during a single patient breath in a conventional system;

Figure 5b is an illustration of the flow delivered by the ventilator using the exhalation-flow reduction scheme of the present invention.

As is shown in the drawings, which are included for purposes of illustration and not by way of limitation, the invention is embodied in a system for flow triggering a breath support ventilation system which reduces the patient work of breathing, provides improved triggering of various types of breath support and allows improved management of the breath support during a breath. The flow-triggering system is used in patient ventilation systems having a source of breathing gas for a patient, a flow-path communicating with the patient, and flow-sensor means for measuring the gas flow to and from the patient. The breathing-gas source provides a predetermined, pre-inspiratory, continuous rate of flow of breath gas to the patient and the flow-sensors measure the rate of gas flow to and from the patient. The system determines the difference between the measured flow rate from the patient and the predetermined rate of delivered gas flow to the patient. The system then generates breath support in the delivered flow of gas when the difference between the flows to and from the patient equals a predetermined threshold or trigger value. The breathing gas may be enriched with a higher concentration of oxygen than normal air. The source of breathing gas may include more than one individual gas source and may also include a device for mixing and controlling the proportions of the individual gases. The system also preferably includes means for determining when exhalation occurs, so that breath support may be discontinued until it is again triggered.

Figure 1 is a schematic of a present system for flow triggering ventilation according to the present invention. In the currently preferred embodiment, the system 10 includes a source of oxygen gas (O₂) 12, which is typically a pressurized tank of oxygen, and a source of air 14, which may also consist of a high-pressure tank of air. The sources of air 14 and oxygen 12 may also typically include pressure regulators. The

air supply source may also comprise an air compressor which supplies air taken from the ambient atmosphere. Other conventional sources of pressurized oxygen and air in hospital or patient-care settings would also be appropriate.

The source of oxygen is connected to a flow meter 16 in the oxygen line 17, and a similar flow meter 18 for the air source 14 is provided in the air line 19. The oxygen line 17 delivers oxygen to its proportional solenoid valve 20, and the air line 19 similarly delivers air to its proportional solenoid valve 22, the two valves releasing oxygen and air for mixing in the mixing chamber 24. Valves other than proportional solenoid valves and mixing means other than mixing chamber 24 may also be appropriate. The mixed gas is delivered from mixing chamber 24 through the airway conduit 26 to the patient wye fitting 27, which is connected to the patient breathing attachment 30 by breathing tube 28. The breathing attachment 30 may be simplified or replaced by other breathing means in certain implementations. In these implementations the breathing-gas flow may be delivered to the patient by means of a breathing tube (artificial airway) or by a breathing mask or other means for delivering breathing gas to the patient's trachea. In either implementation and prior to and immediately after the inspiratory flow, flow meters 16 and 18 monitor the flow of gas to the patient during the continuous flow of gas from the oxygen and air sources (up to and including the time at which the patient's inspiratory flow equals the triggering threshold flow signal) and during exhalation. Exhalation gas from the patient area flows through the exhalation conduit 34 and exhalation flow meter 43. The difference between the sum of flow meters 16 and 18, and exhalation flow meter 43 provides a measurement of flow of breathing air inhaled by the patient from the continuous flow of breathing gas delivered to the patient from the oxygen and air source means. To assist control of the delivery of breathing gas to the patient, the flow-control algorithm may monitor flow sensors 16, 18 and 43. During operation of the flow-triggering phase and for the restoration of the preinspiratory, continuous flow during exhalation and prior to the patient's next inspiration, flow sensors 16, 18 and 43 become primary inputs to the flow-control algorithm prior to the initiation of the inspiratory effort, immediately after the inspiratory effort, and during exhalation when the preinspiratory, continuous flow is being reestablished.

Beginning with and immediately after the patient's inspiratory effort, the flow of breathing gas to the patient will exceed the flow of breathing gas from the patient, and the difference between the flow to and from the patient is compared with a predetermined, "flow-trigger" threshold level. This measurement of flow inhaled by the patient is used for triggering the initiation of pressure-supported inspiration although

other types of breath support routines may also benefit from the flow-triggering method of the invention. Such other patient initiated, support breaths includes those known in the art as pressure control ventilation (PVC), and its variants with volume priority or guarantee and inverse ration ventilation; airway pressure release ventilation (APRV) and its variants BIPAP and synchronized ARPV; proportional assist ventilation (PAV); and volume priority pressure support ventilation, and the like. In a preferred embodiment, prior to return of the exiting or exhalation gases to the ambient atmosphere, said gases are passed through a fluid collector vial 36 and a heated bacteria filter 38 provided in the exhalation conduit line. A pressure transducer 40 for measuring the pressure during both inspiration and exhalation may also be provided in the exhalation conduit 34. The system may also include an exhalation valve 44 to close the system to allow breaths and to open the system for exhalation to the atmosphere, to thereby return the filtered and cleaned exiting gas to the atmosphere from the open ventilator system.

The invention may use other methods for measuring the inhaled flow by the patient from the preinspiratory, continuous flow of breathing gas. A flow meter 32 may be placed between the patient wye 27 and the patient attachment 30 to measure patient inhalation flow directly. Alternatively, or in addition to flow meter 32, a delivery flow meter 41 may be provided in the air way conduit 26 for measuring the flow of mixed breathing gas delivered to the patient, and an exhalation flow meter 42 may be installed in the exiting airway conduit 34 for monitoring the flow of gas from the patient during inspiration effort and exhalation. The difference between flow meters 41 and 42 also provides a measurement of flow inhaled by the patient from the preinspiratory, continuous flow of breathing gas from the source means.

It will be understood by those skilled in the art that any combination of signals from flow meters 16, 18, 32, 41, 42 and 43 may be used for sensing and measuring the flow inhaled by the patient for use as a flow-trigger signal for inspiration.

An electronic control means 46, preferably including a microprocessor for controlling all of the functions of the ventilator control system, is connected to the oxygen-source flow meter 16, the air source flow meter 18, the oxygen proportional solenoid valve 20, the air proportional solenoid valve 22, the patient exhalation flow meter 43, and any additional flow meters (41) in the inspirational airway conduit 26, the patient wye flow meter 32, or flow meters (42) in the exiting or exhalation airway conduit 34. Electronic control means 46 compares the rate of flow to the patient through the patient wye 27 as derived by any

of the previously discussed means, with a predetermined flow threshold level to detect whether the patient's inspiratory effort has met the criterion for trig-

gering pressure support by operation of the proportional solenoid valves 20, 22. The control means 46 also controls the proportional mixing through the proportional solenoid valves 20, 22. The control means 46 also controls the proportional mixing through the proportional solenoid valves 20, 22 and operates to open the exhalation valve 44 and cause the proportional solenoid valves 20, 22 to discontinue pressure support when the exhalation effort of the patient is detected, returning the flow of breathing gas to the patient to the preinspiratory level of continuous flow in readiness for the patient's next inspiratory effort.

The flow triggering of breaths involves monitoring the flow of inhaled gas from the continuous flow of breathing gas delivered to the patient, which reduces the energy required from the patient to initiate a ventilator breath, and turning on the inspiratory pressure support when the patient's inspiratory flow meets the triggering criterion. The continuous, minimal flow of breathing gas delivered into the breathing circuit prior to the initiation of the inspiratory effort serves two functions: First, the continuous flow converts the normally closed breathing-gas circuit into one that is functionally open. Second, the continuous flow establishes a highly stable flow of breathing gas which can be monitored by the flow sensing means to determine when the patient begins his or her inspiratory effort. This flow triggering approach converts the initial work of inspiration from an essentially isometric effort to a quasi-isotonic effort. Both the level of continuous flow and the required change in flow due to inhalation for inspiratory support triggering may be adjusted through the control means.

As previously discussed, the energy expended by a patient while breathing on a mechanical ventilator can be divided into two components. The first component is the energy required to trigger the ventilator to begin the inspiration. The second component is the energy required to maintain adequate gas flow once the ventilator has been triggered to deliver inspiratory support.

A primary purpose of the pressure support mode of ventilation is to reduce the second energy component. This is accomplished by providing a positive pressure level during the inspiratory phase of the breath. This positive pressure may be used to reduce or negate the imposed work due to the resistance of the artificial airway, and/or the resistance and compliance intrinsic to the patient's respiratory system. In extremely weak patients, the application of pressure support can provide sufficient tidal volumes without using assist-control ventilation, and can thereby increase patient comfort while returning to the patient some measure of control over his or her breathing pattern. Patients have been shown to expend less work or energy in breathing when pressure support is used. This can have important implications when weaning patients from the ventilator, since the patient must

then be progressively strengthened to breath without the pressure support to inspiration.

Figures 2a and 2b show traces of pressure over time and flow over time, respectively, as they vary from the patient pressure baseline 50 (Figure 2a) and the patient flow baseline 52 (Figure 2b) for a typical spontaneous, non-pressure supported, ventilator-delivered breath. In Figure 2a, the area under pressure-time trace 53 which is below the pressure baseline 50 represents the work being done by the patient. The portion of the curve 53 in the pressure-time trace between point A and point B at the pressure trigger level 54 depicts the portion of this work required to trigger inspiratory support. The portion of the curve between points B and C represents the remaining work of inhalation 58 required to maintain an adequate gas flow to satisfy the inspiratory demands of the patient. In other terms, the area between B and C represents the work required of the patient to sustain the breath. Note (with respect to the pressure baseline 50) that, as shown in Figure 2a, the pressure is negative throughout inspiration, indicating that the patient is performing work during this entire period. It should also be noted that the peak negative pressure required of the patient is the level 55 noted on Figure 2a. The exhalation phase 60 begins at the end of the inhalation phase. Figure 2b shows the flow rates corresponding to the pressure-time curves of Figure 2a. It is evident that the flow prior to B, the point at which the pressure triggering is effected is very low and that substantial work is still performed by the patient between B and C, even though the pneumatic system was cycled on at B.

Figure 3a and 3b show traces of pressures over time about a patient pressure baseline 62, and flow over time about a flow baseline 64, respectively, for a typical pressure-triggered, pressure-supported breath. Once the breath is triggered at B representing the pressure trigger level 66, the ventilator creates a positive pressure to reduce the patient's work of inspiration. Prior to the inspiration cycle 68, a negative pressure, and therefore an expenditure of energy by the patient, is required to trigger the breath. Pressure support is discontinued when the patient exerts an expiratory effort of when flow into his/her lungs declines to a preselected value. At this point, the patient begins the exhalation phase 70. It may be seen that the flow level at the time of triggering 72 was relatively low, but rapidly increased in response to the pressure support supplied after pressure triggering. However, there remains a substantial amount of work which must be expended by the patient for this scheme as well.

As illustrated in Figures 4a and 4b, the present invention's combination of flow triggering with pressure support (with an appropriate selection of the support pressure) can reduce the energy expenditure by the patient to a virtually negligible level.

Figures 4a and 4b show traces of pressure over time about a patient pressure baseline 74, and flow over time about a flow baseline 78, respectively, for a typical, flow-triggered, pressure-supported breath according to one embodiment of the present invention. Comparison of Figures 3a and 4a shows that the pressure 66 required for pressure triggering is more negative compared with the pressure 76 resulting from flow triggering. The negative pressure component 66 (in the pressure-triggering example of Figure 3), representing the work done by the patient, is substantial, whereas the negative component 76 (with flow-triggering example, Figure 4) is minor. The flow 80 to the patient can be seen to be higher at the flow trigger level in the flow triggered system of Figure 4b than the flow level 72 in the pressure triggered system of Figure 3b. With respect to the flow-triggering traces in Figure 4, both the less negative triggering pressure and the higher inspiratory flows early in the breath, compared to the pressure-triggered traces of Figure 3 result from the physical differences between the flow systems. In the flow-triggered case, the patient inhales from a functionally open system (i.e., the patient's earliest flow demands are met by the preinspiratory, continuous flow), whereas in the pressure-triggered case, the patient inhales from a closed system (i.e., the patient receives no flow until the pressure-trigger threshold is reached). Thus, it can be seen that the combination of flow triggering with pressure support of the present invention reduces the energy expended by the patient to trigger inspiratory support and also reduces the patient energy required to maintain the inspiratory phase. Thus, by combining flow triggering with pressure support according to the present invention, the work done by the patient to trigger pressure-supported breathing is minimized while the appropriate selection of the support pressure allows the patient's inspiratory work to be set at a desired level. From the above, it may be seen that the work associated with the interval A-B in Figures 2 and 3 may be substantially reduced with the present invention as illustrated by the interval A-B of Figure 4. Thus, while the patient work of Figure 3 is lower than that of Figure 2, representing the difference between pressure triggering of flow support and pressure triggering of pressure support, the latter representing a more aggressive technique for support to a pressure triggered system. The present invention further minimizes the patient work compared to these previous strategies.

While pressure support of ventilation has a number of advantages as discussed above, the attendant high pressures in the exhalation limb of the patient's breathing-gas circuit during the exhalation phase of the flow triggered pressure supported breath can be a cause of concern for the patient unless they are carefully controlled. Pressures above the PEEP (baseline pressure value) generally indicate that the

patient's lungs are hyper-inflated. These events can place the patient's diaphragm and accessory inspiratory muscles in a position of relative inefficiency and may impose a higher work of breathing on the patient. If the patient is alert, he/she may also attempt to forcefully exhale to PEEP (baseline pressure value), which also adds extra work to the breath effort. Thus, it would be desirable to maintain the lowest possible pressures in the patient breathing circuit during exhalation. A long-recognized disadvantage of the earlier developed, continuous flow concept was the presence, in the exhalation limb of the patient's breathing-gas circuit, of the practitioner-selected, continuous flow in addition to the patient's own exhalation flow. This constant extra flow elevated the pressure in the patient's breathing-gas circuit (during exhalation), which could also lead to problems similar to those discussed above.

The present invention of flow triggering can be configured to minimize this extra, non-patient generated exhalation flow in the patient's breathing-gas circuit. According to a preferred embodiment of the invention, when the ventilator declares exhalation and (opens the exhalation valve) the pre-inspiratory, continuous flow of breathing gas is set to a minimal value. This minimal value is maintained throughout the most active phase of the patient's exhalation, then it is reset by the ventilator to the specified value for the pre-inspiratory, continuous flow of breathing-gas, in anticipation of the next inspiratory effort.

Figure 5 illustrates the function of this preferred embodiment. Figure 5a illustrates the patient flow above and below baseline in a system of pressure supported breathes as previously described. Figure 5b illustrates the flow support time history delivered by this preferred embodiment, in which the flow is reduced during the early exhalation period and then returned to the practitioner selected continuous base flow. By using this scheme, the over-pressurization of the patient's airway is avoided during the early period exhalation, thus reducing the work performed by the patient and limiting the undesirable effects described above.

It may be seen from the foregoing description that the system and method of the present invention allow for reduction of patient discomfort and work of ventilator supported breathing by maintenance of a preinspiratory, continuous flow of breathing gas to the patient and by flow triggering of inspiratory support. In combination with pressure support to the patient during the inspiration effort, the flow triggering strategy of the invention offers significant improvements in providing breath support to patients having weakened respiratory capabilities.

Claims

1. A method of flow triggering of breath support ventilation in a functionally open breathing-gas circuit, which method comprises delivering a predetermined rate of flow of breathing gas from a source (12, 14) to a patient and generating breath support in the determined flow of gas when the patient inhales; characterised in that inhalation is determined by measuring the change in the rate of gas flow in said ventilation flow path due to inhalation; breath support in said delivered flow of gas is provided when said change in the rate of gas flow due to inhalation exceeds a predetermined threshold value; and restoring the preinspiratory, continuous flow of breathing gas to a predetermined value before the patient's next inspiratory effort.
2. The method of Claim 1, characterised in that said flow path includes an inhalation (26) and exhalation flow path (34) into and from said patient and said source of breathing gas and said flow path meets at a junction (27) communicating with the patient, and the step of determining the rate of gas flow in said flow path comprises measuring gas flow at the portion of the junction (27) communicating with the patient.
3. The method of Claim 1, characterised in that said flow path includes an exhalation flow path (34) from said patient and an inhalation flow path (26) to the patient and in that said step of determining the rate of gas flow into and from said patient comprises performing measurements at at least one portion in the inhalation flow and at at least one position in the exhalation flow.
4. The method of Claim 1, characterised in that said flow path includes an exhalation flow path (34) from said patient, and said measurement of said change in the rate of gas flow in said flow path is measured in at least one location in said exhalation flow path (34).
5. The method of Claim 1, further including the step of discontinuing said breath support when the flow rate in said flow path drops below a predetermined value.
6. The method of Claim 1, further including the step of discontinuing said breath support when the pressure in said flow path rises above a threshold value.
7. The method of any of Claims 1 to 6, further including the step of reducing the flow rate provided by

the ventilator during the early stages of the patient's exhalation process for a predetermined period of time.

8. The method of any one of Claims 1 to 7, wherein said breath support comprises pressure support, pressure control ventilation and variants thereof, airway pressure release ventilation and variants thereof, proportional assist ventilation, or volume priority pressure support ventilation. 10

9. A system of flow triggering breath support ventilation for use in a functionally open breathing-gas circuit having means to supply a predetermined, preinspiratory, continuous gas flow from a source of breathing gas (12, 14) to a patient via a flow path (17, 19, 26, 34) characterised by flow sensor means (16, 18, 32, 41, 42, 43) for measuring the rate of gas flow in said flow path due to inhalation; means (46) responsive to said flow sensor means (16, 18, 32, 41, 42, 43) for generating breath support in said delivered flow of gas when said change in the rate of gas flow due to inhalation exceeds a predetermined value; and means (46) for restoring the preinspiratory, continuous flow of a breathing gas to its predetermined value before the patient's next inspiratory effort. 20

10. The system of Claim 9, characterised in that said flow path includes an inhalation (26) and exhalation (34) flow path into and from said patient, and said inhalation and exhalation flow paths form a junction (27) communicating with the patient, and wherein said flow sensor means (32) for measuring the rate of gas flow into said patient is located at said junction (27). 30

11. The system of Claim 9, characterised in that said flow path includes an exhalation flow path (34) from said patient, an inhalation flow path (26) to said patient, and said flow sensor means for determining the change in the rate of gas flow into and from said patient comprises at least one flow sensor (42) located in at least one location in said exhalation flow path (34) and at least one other flow sensor (41) in at least one other location in said inhalation flow path (26). 40

12. The system of Claim 9, further comprising a plurality of flow sensor means (16, 18, 32, 41, 42, 43) and a control means (46) for measuring the gas flow rate at at least n of the flow sensor means (16, 18, 32, 41, 42, 43). 45

13. The system of Claim 9, further comprising a plurality of flow sensor means (16, 18, 32, 41, 42, 43) and a control means (46) for measuring the gas flow rate at at least n of the flow sensor means (16, 18, 32, 41, 42, 43). 50

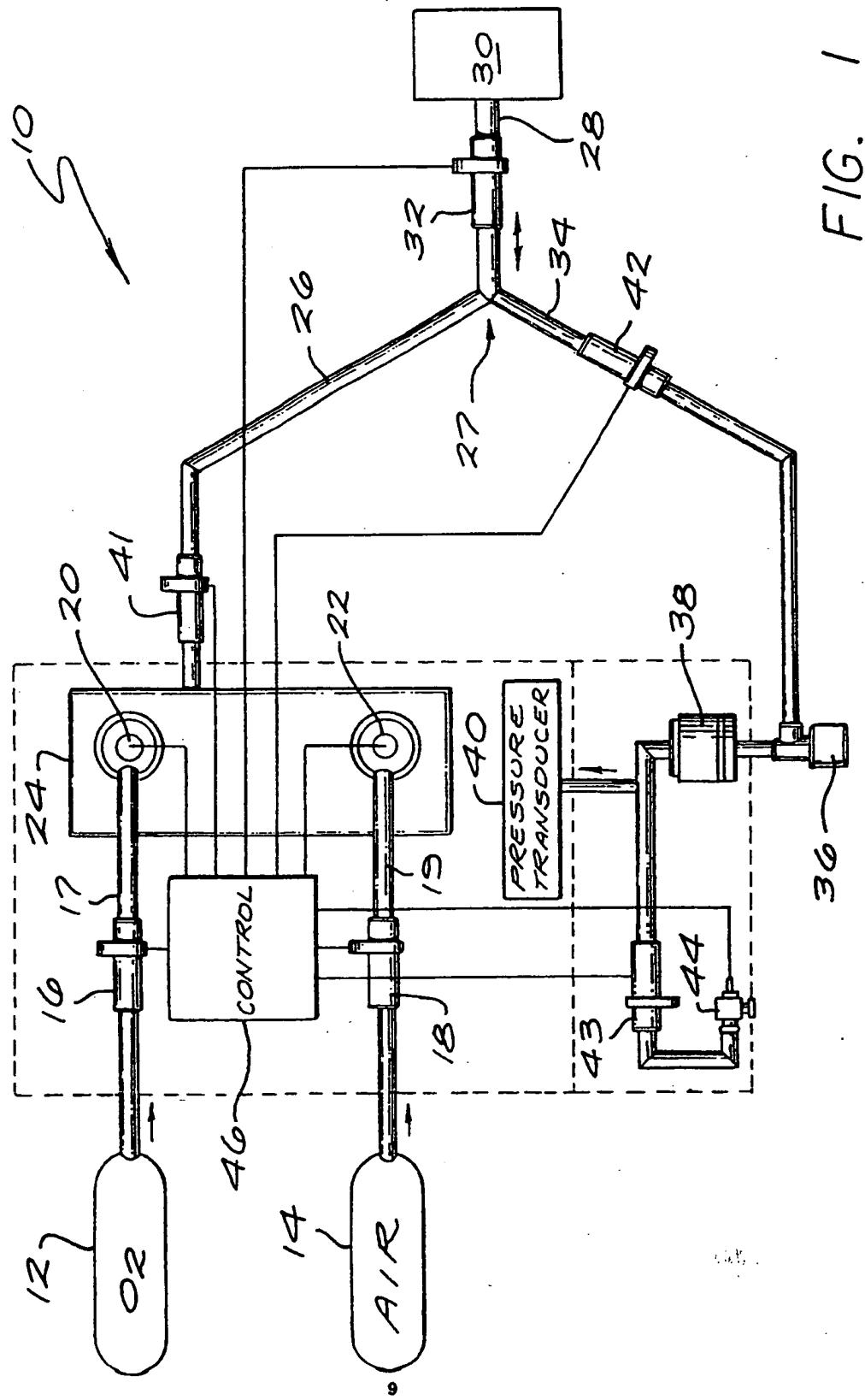
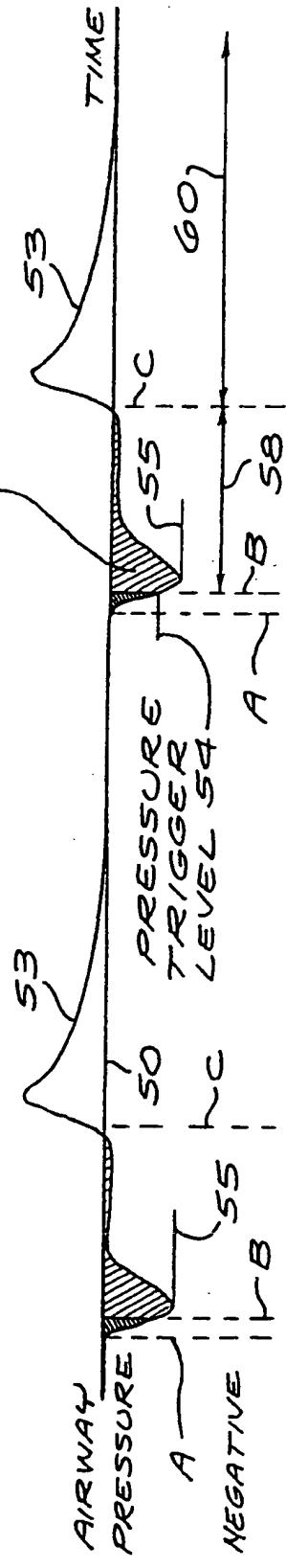


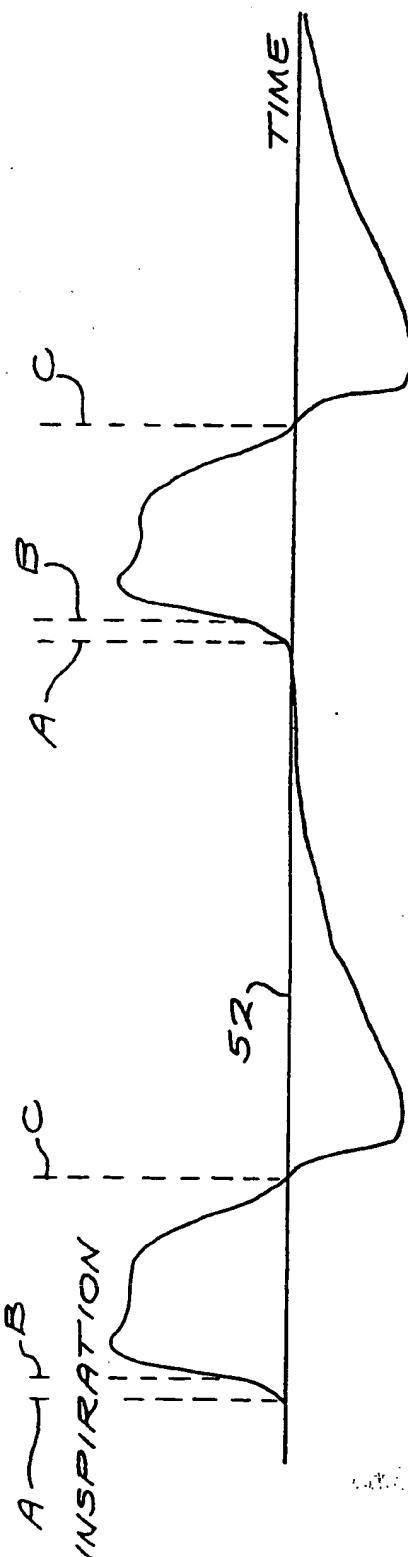
FIG. 1

FIG. 2a

POSITIVE
WORK BEING DONE
BY PATIENT



10



EXHALATION

FIG. 2b

FIG. 3a

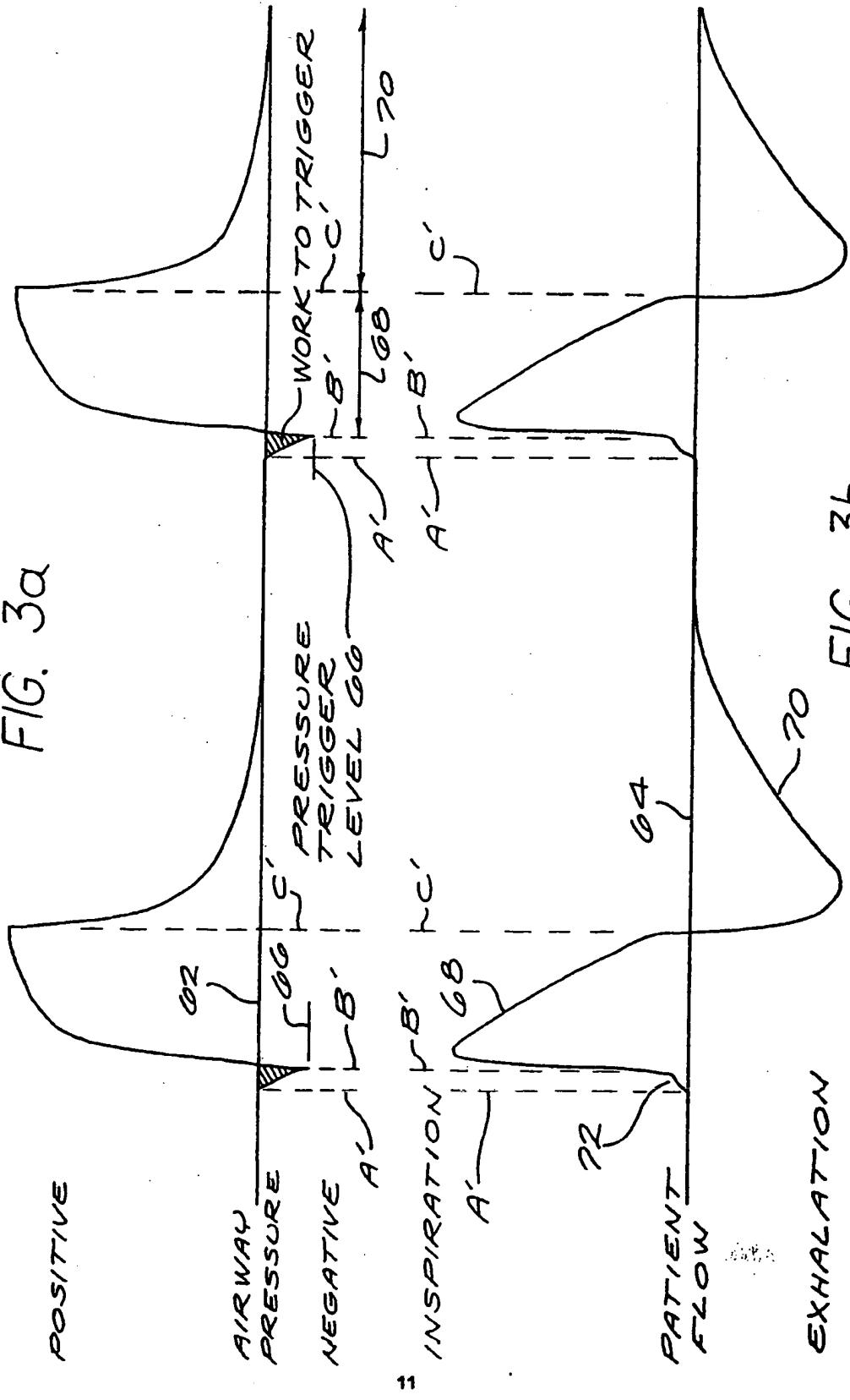


FIG. 3b

FIG. 4a

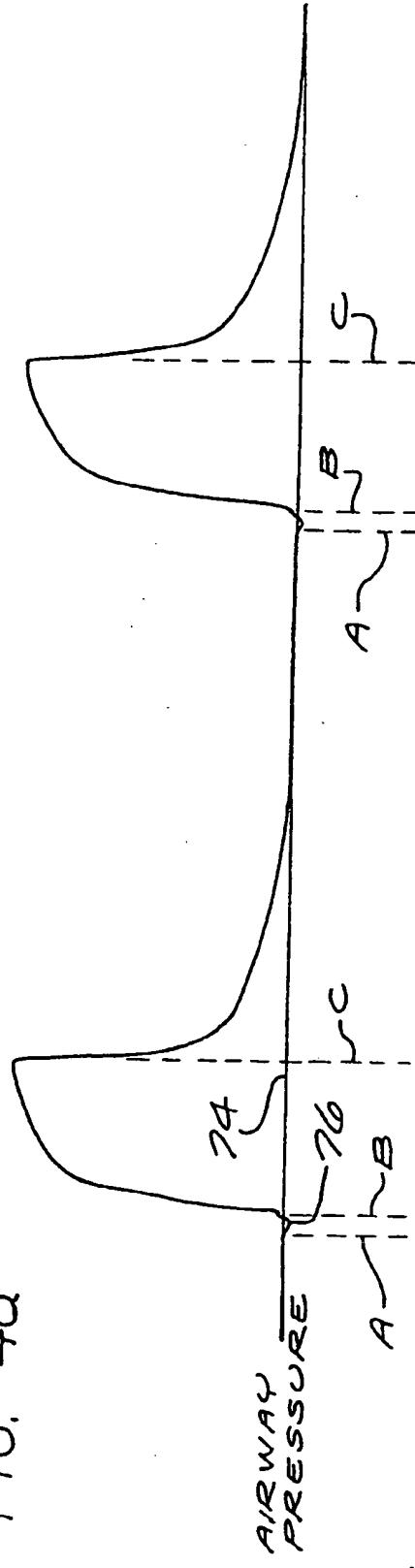


FIG. 4b

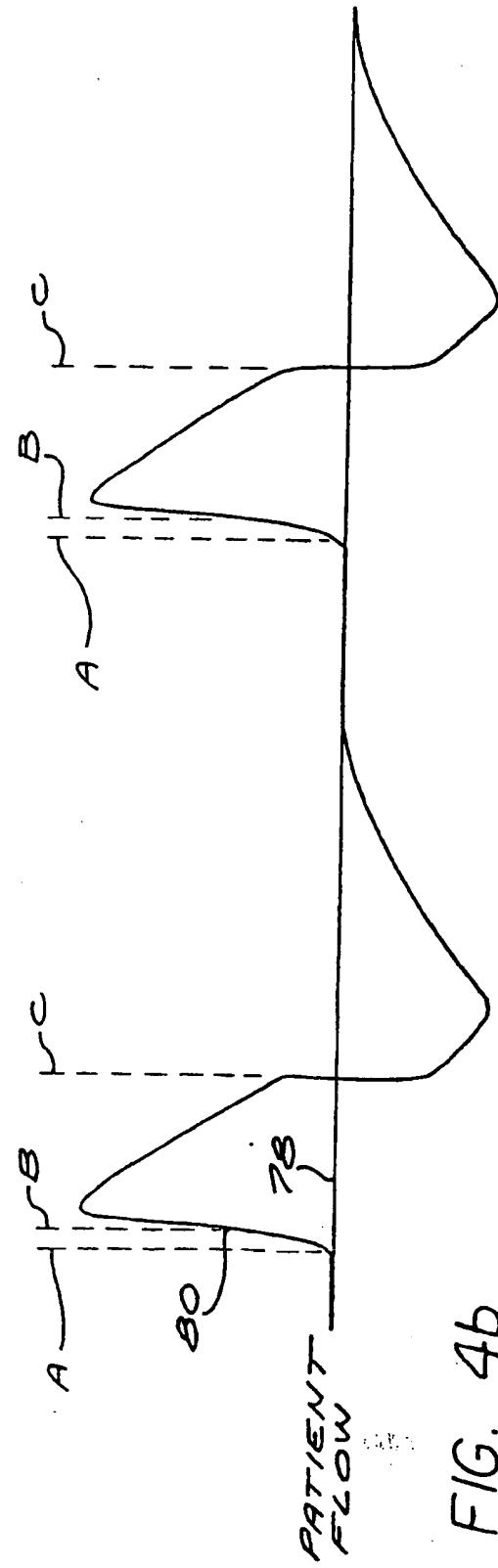


FIG. 5a

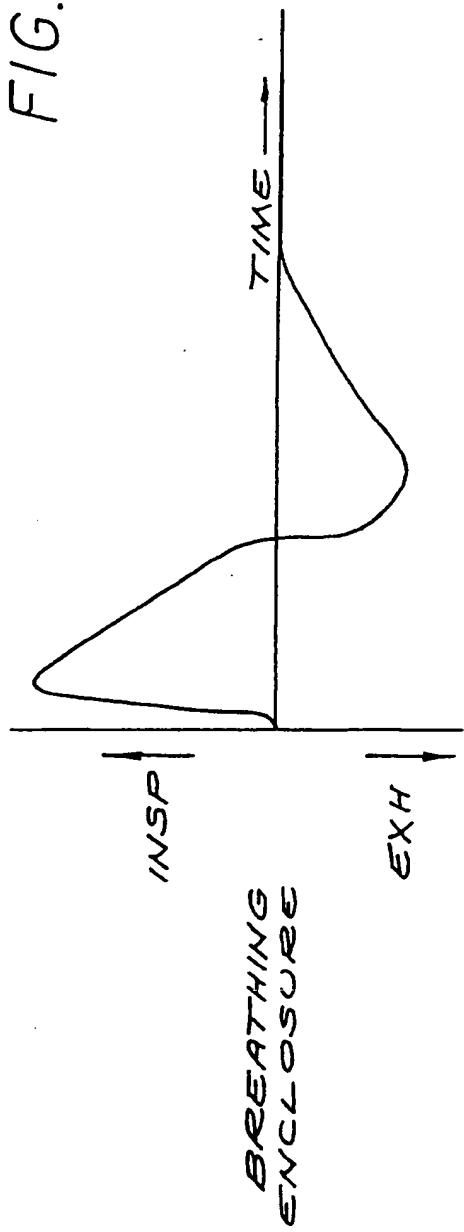


FIG. 5b

